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Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, in respect to safety and effectiveness is summarized below.

Submitted by:

Bryan A. Lisa
Regulatory Affairs Project Manager
ETHICON, Inc., A *Johnson & Johnson* Company
Route 22 West, PO Box 151
Somerville, NJ 08876

MAY 15 2008

Name/Classification of Device:

Class II in 21 CFR § 878.3300, Surgical Mesh (FTL)
Class I in 21 CFR § 878.4800, Manual surgical instrument for general use

Trade Name:

GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems
GYNECARE PROLIFT+M* Total, Anterior, and Posterior Pelvic Floor Repair Systems

Predicate Devices:

- **GYNECARE GYNEMESH PS* PROLENE* Soft Mesh** (ETHICON, Inc.) – K013718
- **ULTRAPRO* Mesh** (ETHICON, Inc.) – K033337
- **AMS APOGEE Vault Suspension System** (American Medical Systems, Inc.) – K040537
- **AMS PERIGEE System** (American Medical Systems, Inc.) – K040623

Statement of Intended Use:

The GYNECARE PROLIFT* Total, Anterior, and Posterior Pelvic Floor Repair Systems, through the placement of GYNECARE GYNEMESH PS* PROLENE Soft Mesh, are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

The GYNECARE PROLIFT+M* Total, Anterior, and Posterior Pelvic Floor Repair Systems, through the placement of GYNECARE GYNEMESH M* Partially Absorbable Mesh, are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Device Description:

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut non-absorbable mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

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REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

The GYNECARE PROLIFT+M Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut partially absorbable mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Summary of Technological Characteristics of New Device to Predicate Devices:

The modified devices have similar technological characteristics as the predicate devices.

GYNECARE PROLIFT: Like currently marketed devices, the implantable component is a sterile, mesh implant intended for the repair of pelvic floor defects. The mesh implant component of the proposed device is made of nonabsorbable polymers, which are identical to those found in GYNECARE GYNEMESH PS, currently marketed by ETHICON, Inc.

GYNECARE PROLIFT+M: Like currently marketed devices, the implantable component is a sterile, mesh implant intended for the repair of pelvic floor defects. The mesh implant component of the proposed device is made of nonabsorbable and absorbable polymers, which are identical to those found in ULTRAPRO Mesh, currently marketed by ETHICON, Inc.

Performance Data:

Biological reactivity of the materials has been assessed using methods specified in ISO 10993-1, and the materials were found to be acceptable for their intended uses. Results of functional performance testing (bench and cadaver testing) indicate that the proposed device meets or exceeds all functional requirements, based on FDA's Guidance Document "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh". Preclinical modelling was used to evaluate procedural performance of the systems.

Conclusions:

Based on the similarities to the predicate devices identified in this submission, we conclude that the modified device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.

* Trademark of ETHICON, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Ethicon, Inc.
% Mr. Bryan A. Lisa
Route 22 West
P.O. Box 151
Somerville, New Jersey 08876

Re: K071512
Trade/Device Names: Gynecare Prolift™ Total, Anterior, and Posterior Pelvic Floor Repair Systems; Gynecare Prolift +M™ Total, Anterior, and Posterior Pelvic Floor Repair Systems
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 22, 20008
Received: February 25, 2008

Dear Mr. Lisa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071512

Indications for Use

510(k) Number (if known): K071512

Device Name: GYNECARE PROLIFT* and GYNECARE PROLIFT+M* Total, Anterior, and Posterior Pelvic Floor Repair Systems

Indications for Use:

The GYNECARE PROLIFT* Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

The GYNECARE PROLIFT+M* Total, Anterior, and Posterior Pelvic Floor Repair Systems, through the placement of GYNECARE GYNEMESH M* Partially Absorbable Mesh, are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

*Trademark.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature] for [illegible]

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071512